

### **REMARKS**

Claims 8-32 and 34 are pending. Claims 8-24 and 33 are cancelled with out prejudice. Claims 25, 26 and 34 are newly amended. Claims 35-38 are newly added. The amendments find support in the claims as originally filed and in the specification. No new matter is added.

Specifically, support for newly added claims 35 and 36 includes page 5, lines 1-27 of the specification. Support for newly added claim 37 includes page 6, lines 1-3, while support for newly added claim 38 is found on page 2, lines 1-13.

### ***Drawings***

The office action indicates that that new corrected drawings in compliance with 37 C.F.R. 1.121(d) are required in this application. Accordingly, Applicant has submitted herein a new set of drawings.

### ***Claim Objections and Rejections***

The Office Action states that claim 25 is objected to because of the following informalities: the claim does not appear to be a complete sentence because it is lacking the positive precitation of the word “and between steps (a) and (b).

Accordingly, Applicant has amended claim 25 by inserting the word “and” between steps (a) and (b).

The Office Action states that claim 34 is objected to because a multiple dependent claim should refer to other claims in the alternative only, and refers to MPEP § 608.01(n). The office Action further states that claim 34 has not been further treated on the merits.

Applicants respectfully traverse on the grounds that claim 34 as it was prior to the amendment did refer to other claims in the alternative only. Claim 34 recites “The method of **any one of claims 25 and 33**, wherein the HPV is high risk HPV (hrHPV).”(emphasis added).

MPEP § 608.01(n) provides a list of acceptable multiple claim wording, which includes the phrase "any one of claims 1, 2, and 3," see excerpt below.

**"A. Acceptable Multiple Dependent Claim Wording**

Claim 5. A gadget according to claims 3 or 4, further comprising ---

Claim 5. A gadget as in any one of the preceding claims, in which ---

Claim 5. A gadget as in any one of claims 1, 2, and 3, in which ---"

Because the language of claim 34 is properly formatted along the lines of the third example listed above, claim 34 properly refers to other claims in the alternative, and should have been acted on by the Examiner. However, claim 34, as newly amended, is no longer a multiple dependent claim, thereby rendering this objection moot.

***Claim Rejections – 35 USC § 102***

The office action indicates that claims 25-27 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Fournier (6,155,990)

Applicant respectfully traverses. Anticipation requires that the purported prior art reference disclose each and every limitation of the claim. *Atlas Powder Company et al. v. IRECO, Incorporated et al.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999). Applicant contends that Fournier does not teach each and every limitation of the instant claims.

Specifically, Fournier does not teach a method for detecting HPV in a vaginal specimen comprising the use of a specimen collection device comprising a **brush comprising bristles**. The collecting device used in the methods taught by Fournier comprises a telescoping cylindrical tampon-like cardboard tube which houses a specimen gathering **sponge**, see column 3, lines 23-27. The referenced sponge with its absorbant properties is distinct from the instantly claimed brush comprising bristles as recited in newly amended claims. The bristles lack the absorbant qualities of a sponge, but are also less easily contaminated.

There are several advantages of using a collection device that contains bristles as opposed to a sponge for detecting HPV in a vaginal specimen, including: (a) the bristles will not be as likely to soak up as much extracellular material as the sponge, the extracellular material reducing the sensitivity of the method by increasing the background, (b) the sample components are likely to be more easily removed from the bristles, thereby increasing the sensitivity of the assay, and (c), the bristles are likely to be easier to clean than a sponge.

Newly added claims 37 and 38 further distinguish the instant method from that of Fournier, by containing the respective limitations that the bristles be made of a flexible material, e.g., polyethylene, polyurethane, polyvinyl chloride, polysiloxanes or nylon, and that the device not use absorbant material ( e.g., a sponge) to collect the sample.

Because the method for detecting human papilloma virus taught by Fournier does not encompass the use of a specimen collection device having a brush with bristles as required in the instant claims, Applicants contend that Fournier is not an anticipatory reference for the instant newly added claims, all of which encompass the collection device comprising a brush with bristles.

In view of the claim amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of the instant rejection.

#### ***Claims Rejections – 103***

The office action states that claims 28-32, are obvious over Fournier, in view of Zavada (US2003/0049828).

Applicants respectfully traverse on the grounds that neither Fournier alone, nor when combined with Zavada, teach all the limitations of the instant newly added claims. Applicants submit that for a determination of obviousness to be proper, the prior art reference (or references when combined) must teach or suggest *all the claim limitations*. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974).

As discussed in the rebuttal to the 102 rejection, Fournier does not teach a method for detecting HPV in a vaginal specimen comprising the use of a specimen collection device comprising brush with bristles, as required by the newly amended claims.

Zavada et al.'s teaching of methods comprising assaying bodily fluids for the presence of MN proteins using antibodies and proteins does not make up this difference.

Therefore, Applicants contend that the teachings of Fournier, either alone or in combination with Zavada, do not teach all the limitations of the newly added instant claims.

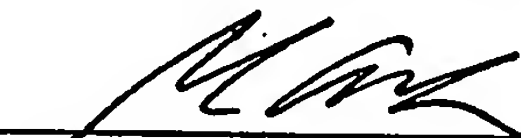
In view of these distinctions of the instant invention from both the references cited in the Office Action and the references disclosed in the background section of the instant specification, Applicants contend the instant newly added claims are not anticipated or made obvious by these references.

### ***Conclusion***

Applicant submits that all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicant's attorney/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney/agent of record.

Respectfully submitted,

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